JUN 2 6 2000

K000992

ADMINISTRATIVE INFORMATION

Manufacturer Name:	MacroPore, Inc. 6740 Top Gun Street San Diego, CA 92121
Official Contact:	Kenneth K. Kleinhenz Director of Regulatory Affairs Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Plate, Bone
Trade/Proprietary Name:	MacroPore*DX* Distractor System

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 872.4760 Bone Plates are intended to stabilize fractured bone structures in the oral cavity and are classified as Class II. Bone Plates have been assigned Product Code JEY.

INTENDED USE

MacroPoreDX Distractor System, in conjunction with the Leibinger Cohen MID Distractor screw, is intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, and hemifacial microsomia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

DEVICE DESCRIPTION

Design Characteristics

The MacroPore*DX* Distraction System consists of biodegradable bone fixation plates and screws (Adapter Plates, Distraction Plates, Consolidation Plates, and screws) fabricated from polylactic acid. The MacroPore*DX* Distraction System is used in conjunction with existing metallic distractor devices for trauma and reconstructive procedures. MacroPore*DX* Distraction System is available in various sizes and thickness for osteotomy and segment advancement procedures. The Adapter Plates allow the MacroPore*DX* Distraction System to be used in conjunction with existing metallic distractor devices. The Distraction Plates maintain stability of the region during the advancement procedure while the Consolidation Plates maintain stability during the healing or consolidation period.

MacroPore*DX* Distraction and Consolidation Plates can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore*DX* Distraction and Consolidation Plates to the desired shape or size. Distraction and Consolidation Plates are fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. Distraction and Consolidation Plates are used in conjunction with screws to fixate the MacroPore*DX* Distraction System and prevent dislocation.

MacroPore*DX* Distraction and Consolidation Plates are provided in sheets of 20 x 20 mm to 120 x 120 mm and will be provided in other sizes as needed for particular surgical procedures. The pore size ranges from 500 microns to 3000 microns in diameter, with pores distributed uniformly throughout the sheet in an offset or aligned pattern. The thickness of the MacroPore*DX* Distraction and Consolidation Plates ranges from 1.0 mm to 2.0 mm according to the region to be treated.

Material Composition

The MacroPore*DX* Distraction System is fabricated from polylactic acid.

In Vitro Testing

Characterization of the effects on inherent viscosity when the raw material is processed into MacroPore*DX* Distraction System verifies the amorphous nature of the MacroPore*DX* Distraction System. Important properties of the material, such as inherent viscosity and the amorphous nature of the material, are preserved and not significantly effected by the manufacturing process. The processing of the material also determined that there was no significant lot-to-lot variation in the product's inherent viscosity when different lots of raw material are utilized

Because the MacroPore*DX* Distraction System is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of the MacroPore*DX* Distraction System is not expected to have a significant effect on its mechanical properties.

Accelerated aging testing was performed on MacroPore*DX* Distraction System. Simulated *in vivo* accelerated testing indicates that the MacroPore*DX* Distraction System retains all of its strength for the first 9 months and a steadily decrease in strength to zero after approximately 18 months.

Mechanical testing was performed on the MacroPore*DX* Distraction System and determined to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore*DX* Distractor System shares indications and design principles with the following predicate device which has been determined by FDA to be substantially equivalent to a pre-amendment device: Howmedica Leibinger Cohen Distractor-MID System, a Class II medical device that was cleared for marketing in the United States under (K972154).

Indications For Use

The MacroPore*DX* Distractor System and the predicate device have substantially equivalent indications for use statements as the MacroPore*DX* Distractor System's indications for use statement is essentially a subset of the predicate's indications. MacroPoreDX Distractor System, in conjunction with the Leibinger Cohen MID Distractor screw, is intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, and hemifacial microsomia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

Design and Materials

The physical design and functional characteristics of the MacroPore*DX* Distractor System and the predicate device are substantially equivalent. The design features of the MacroPore*DX* Distraction System and the predicate device are substantially equivalent as both devices attach to bone and move the bone outward when mechanical distraction forces are applied. In addition to moving bones, both the MacroPore *DX* Distraction System and the predicate device are substantially equivalent as both devices stabilize fractured bone structures in the oral cavity. The MacroPore *DX* Distraction System and the predicate device are also substantially equivalent as both devices utilize the shearing forces of screws when mechanical distraction forces are applied. The titanium device differs from MacroPore*DX* Distractor System device in that it may be left in place permanently or must be removed surgically, whereas the polymer devices are intended to be metabolized by the body and do not require removal.

SUMMARY : TABLE OF SUBSTANTIAL EQUIIVALENCE

	Subject Device	Predicate Device	Related Device	
	MacroPore MacroPore*DX* Distractor System	**Howmedica Leibinger Cohen Distractor-MID System (K972154)**	**MacroPore Protective Sheet (Protego System) (K972913)**	**MacroPore Protective Sheet (K983360)**
Intended Use	MacroPoreDX Distractor System, in conjunction with the Leibinger Cohen MID Distractor screw, is intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, and hemifacial microsomia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.	The product is intended for use in the treatment of cranial, midface, or mandibular conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, hemifacial microsomia, and mandibular micrognathia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial, midfacial, or mandibular bones.	MacroPore Protective Sheet is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton: 1. Comminuted fractures of the naso-ethmoidal and infraorbital areas 2. Comminuted fractures of the frontal sinus wall 3. Trauma of the midface or craniofacial skeleton 4. Reconstructive procedures of the midface or craniofacial skeleton. The system is not intended for use in the mandible and/or for full load bearing procedures.	MacroPore Protective Sheet is intended to facilitate healing in trauma, reconstruction and bone augmentation procedures of the mandible. The following specific indications are included: to maintain the relative position of bony fragments in trauma and bone graft porcedures, and to contain and prevent migration and shifting of autograft, allograft and/or bone graft substitutes that may be necessary in reconstructive procedures.
Design	Resorbable screws, Adapter Plate for metallic distractor, and various size fixation plates for distraction and consolidation.	1.6mm mini screws and an adjustable distractor with feet to attach the distractor to various mini fixation plates.	Plates, screws, protective sheet mesh, and tacks of various shapes and sizes.	Sheets of 0.50 – 2.0 mm thickness, sizes 20 x 20 mm to 120 x 120 mm or as required.
Material	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	100% titanium	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous	Poly (L-lactide-co-D,L-lactide) 70:30, amorphous
Product Code	JEY	JEY	HRS and HWC	JEY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2000

Mr. Kenneth K. Kleinhenz
Director, Regulatory Affairs
MacroPore, Incorporated
6740 Top Gun Street
San Diego, California 92121

Re: K000992
Trade Name: MacroPore*DX* Distractor System
Regulatory Class: II
Product Code: MQN
Dated: March 27, 2000
Received: March 28, 2000

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000992

Device Name: **MacroPore*DX* Distractor System**

Indications for Use:

MacroPore*DX* Distractor System, in conjunction with the Leibinger Cohen MID Distractor screw, is intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, and hemifacial microsomia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

M.E. Gaydos for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000992